

JAN 20 1998



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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,167,242 was filed on November 21, 1997, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, NICOTROL® (nicotine), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent may NOT be eligible for extension of the patent term under 35 U.S.C. § 156.¹ While applicant argues (see pages 27-32 of the application for patent term extension and the declaration of Anders Sjöholm) that the active ingredient is gaseous or vapor phase nicotine, not merely nicotine, this argument is not persuasive. Nicotine vapor is a mixture of nicotine and air, however, the component (active ingredient²)

¹FDA's Drug Approval Listing for May 1997 states:

Original New Drug Applications
Original Application #: 020714
Approval Date: 02-MAY-97
Trade Name: NICOTROL
Chemical Type: 3
Therapeutic Potential: S
Dosage Form: INHALATION
Applicant: PHARMACIA AND UPJOHN CO
Active Ingredient(s): NICOTINE
OTC/RX Status: RX
Indication(s): Aid to smoking cessation

²21 CFR 60.3(b)(2) defines active ingredient as:

any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

thereof that is "intended to furnish pharmacological activity" is nicotine. Accordingly, the prior approval of nicotine for commercial use or sale is understood to preclude patent term extension based upon the regulatory review of NICOTROL®. Furthermore, despite applicant's arguments to the contrary (see pages 33-38 of the application for patent term extension and the declaration of Anders Sjöholm), the approval date of NICOTROL® appears to have been May 2, 1997 not September 24, 1997, the date claimed by applicant.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).



Karin Tyson
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Office of the Deputy Assistant Commissioner
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